K123059 1/2

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

MAR 4 2013

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the INBONE® Total Ankle System.

(a)(1). Submitted By:	Wright Medical Technology, Inc. 5677 Airline Road Arlington, TN 38002
Date:	September 27, 2012
Contact Person:	Ryan Bormann Regulatory Affairs Specialist II (901) 867-4409
(a)(2). Proprietary Name:	INBONE® Total Ankle System
Common Name:	Ankle Prosthesis
Classification Name and Reference:	21 CFR 888.3110 – Class II
Device Product Code, Device Panel:	HSN: Orthopedic
(a)(3). Predicate Device:	K051023 INBONE® Total Ankle K103374 INBONE® Total Ankle K100886 INBONE® II Total Ankle

(a)(4). Device Description

The INBONE® implant is a total ankle replacement (TAR) that is made of several specific components. A key concept of the INBONE® device is its modularity. Based on patient anatomy, a number of component sizes can be optioned for best fit. These modular components include the tibial stem components, the tibial tray, the poly bearing, the talar dome, and the talar stem. Subject of this submission is an expansion of labeling while Wright is also notifying FDA of additional implant sizes.

(a)(5). INTENDED USE

The INBONE® Total Ankle is intended to give a patient limited mobility by reducing pain, restoring alignment and replacing the flexion and extension movement in the ankle joint.

INDICATIONS

The INBONE® Total Ankle is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.

The INBONE® Total Ankle is additionally indicated for patients with a failed previous ankle surgery.

CAUTION: The ankle prosthesis is intended for cement use only.

(a)(6). Technological Characteristics Comparison

(b)(1). Substantial Equivalence – Non-Clinical Evidence

- Performance fatigue testing has shown that the extended total tibial stem length is substantially equivalent to previous performance tests.
- Through mechanical analysis the new tibial stem diameter and shorter total tibial stem length do not represent a new worst-case.
- Through analysis the new poly bearings do not represent a new worst-case and are substantially equivalent to previously licensed devices.
- Analyses of computed tomography scans were used to support the larger sized stems.

(b)(2). Substantial Equivalence – Clinical Evidence

N/A

(b)(3). Substantial Equivalence – Conclusions

The design characteristics of the subject system do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject device system can be expected to perform at least as well as the predicate systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 4, 2013

Wright Medical Technology, Incorporated
% Mr. Ryan Bormann
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

Re: K123059
Trade/Device Name: INBONE I® and INBONE II® Total Ankle
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSN
Dated: January 28, 2013
Received: January 30, 2013

Dear Mr. Bormann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123059

Device Name: INBONE® I and INBONE®II Total Ankle

Indications For Use:

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The INBONE® Total Ankle is additionally indicated for patients with a failed previous ankle surgery.

CAUTION: The ankle prosthesis is intended for cement use only.

Prescription Use **xxx** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Casey L. Hanley, Ph.D.

Division of Orthopaedic Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)